



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,889	01/19/2001	Rosalie Luiten	L0461/7104	9782

7590 08/05/2005

John R. Van Amsterdam  
Wolf, Greenfield & Sacks, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, MA 02210-2211

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/766,889

Applicant(s)

LUITEN ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 8, 79 and 81-85.  
Claim(s) withdrawn from consideration: \_\_\_\_\_

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.


**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see "Other" below.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
13. ☒ Other: See Continuation Sheet.

*Marianne DiBrino* 8/1/05

Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection of record of claims 8 and 81-85 under 112, 1st paragraph written description, the rejection of record of claims 8 and 79-85 under 112, 2nd paragraph.

Continuation of 13. Other: The rejection of claims 8, 79 and 81-85 would be maintained over the proposed claims for the reasons of record. Applicant's arguments have been fully considered but are not persuasive. It is the Examiner's position that the motivation exists in the art to use the EADPTGHSY peptide that was known to bind to HLA-A1 with peptides from the same or different TAAs (tyrosinase and MAGE are both melanoma TAAs and would be useful in the same composition) that bind to other HLA restriction elements in the same composition to broaden immunological coverage among HLA-diverse populations as enunciated in the instant rejection. Regardless that the EADPTGHSY peptide was not known to bind to HLA-B35 in the art references, administration of the composition comprising the EADPTGHSY peptide to an individual in a population, said individual being positive for both HLA-A1 and HLA-B35, the EADPTGHSY peptide would elicit an immune response in that individual, since it is an expected property that the peptide would stimulate either a humoral or cellular response in said subject since, in the latter instance, it binds to both HLA restriction elements. In addition, if one of ordinary skill in the art were to administer the composition of the combined references to individuals who were not HLA tested prior to administration because as the art teaches, peptides are included in the composition that would induce broad coverage in populations, in any HLA-B35 positive individuals in the said population, the EADPTGHSY peptide would induce an immune response restricted by HLA-B35. Also, Rammensee et al teach the EADPTGHSY peptide has preferred residues at some positions and further teach CTL epitopes that have the P1 E, P3D, P7 H and P8 S as does the EADPTGHSY peptide, and teach an HLA-B35 binding peptide that has P6 G as does the EADPTGHSY peptide. While the Examiner does not consider this sufficient motivation to administer the EADPTGHSY peptide to an HLA-A1 negative individual who is HLA-B35 positive to induce an HLA-B35-restricted immune response, it would have been obvious to one of ordinary skill in the art that a peptide with a common P9 anchor residue along with preferred residues might bind to other HLA restriction elements besides HLA-A1 if those other HLA restriction elements bind peptides having a common primary anchor residues as well as many preferred or acceptable residues at other positions in the peptides. This would provide additional motivation for including it in a composition because minimally it does bind to its known restriction element which is sufficient motivation by itself to include it in the composition, and it might also bind to other restriction elements, in this case to use the EADPTGHSY peptide because it is an immunogenic peptide that binds to HLA-A1, whereas a peptide that has no common anchor or preferred or permitted residues would not be expected to bind to another HLA molecule. In addition, the proposed claims do not recite that the immune response in the HLA-B35 positive subject must be HLA-B35 restricted. Further, with respect to Applicant's arguments to '037, it was known in the art at the time the invention was made that not all epitopes conformed to a canonical motif for binding to an HLA molecule, for example, the cited Rammensee et al reference teaches an HIV-1 env gp41 606-614 epitope with the sequence TAVPWNASW that is HLA-B35 restricted that does not possess either the P2 P or the P9 (Y, F, L, M or I) primary anchor residues, but has preferred P2 A and P4 P.

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600